

[REDACTED]

[REDACTED]

II. TAXONOMY

A. Recipient Microorganisms

[REDACTED]

B. Donor Microorganisms

[REDACTED]

[REDACTED] This bacterium naturally occurs in the human gastro-intestinal tract and in a range of fermented food products, such as sauerkraut, olives, wine, dry sausage and probiotics.

[REDACTED] It is common in temperate and subtropical climates but is mostly associated

[REDACTED]

[REDACTED] The typical habitat for [REDACTED] is the lower intestines of humans and other warm-blooded animals.

III. PRODUCTION VOLUME

The primary commercial product will be fluid bed dried, active modified yeast; commercially referred to as Active Dried Yeast (ADY). The anticipated production volumes for the active dry yeast were given by quarters as follows:

	2016	2017	2018	2019
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	-
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	-

*Amounts in metric tons

The modified [REDACTED] will be grown, concentrated, dried and packaged at:
[REDACTED]

IV. HISTORY OF USE

[REDACTED] has an extensive history of use in the area of food processing. Also known as Baker's Yeast or Brewer's Yeast, this organism has been used for centuries as a leavening agent for bread and as a fermenter of alcoholic beverages. The risk assessment of [REDACTED] for the 5(h)(4) Tiered Exemptions Final Risk Assessment for *S. cerevisiae*: (<http://www.epa.gov/oppt/biotech/pubs/pdf/fra002.pdf>) concluded that this yeast presents low hazards to human health and to the environment, and thus, this yeast qualified as an eligible recipient microorganism for the Tier I Exemption. However, the use of Tier I-qualifying microorganisms at multiple facilities requires transport of the microorganism which is not fall in the realm of the Tier I Exemption. Consequently, EPA has reviewed this recipient microorganism in a number of recent MCANs [REDACTED]

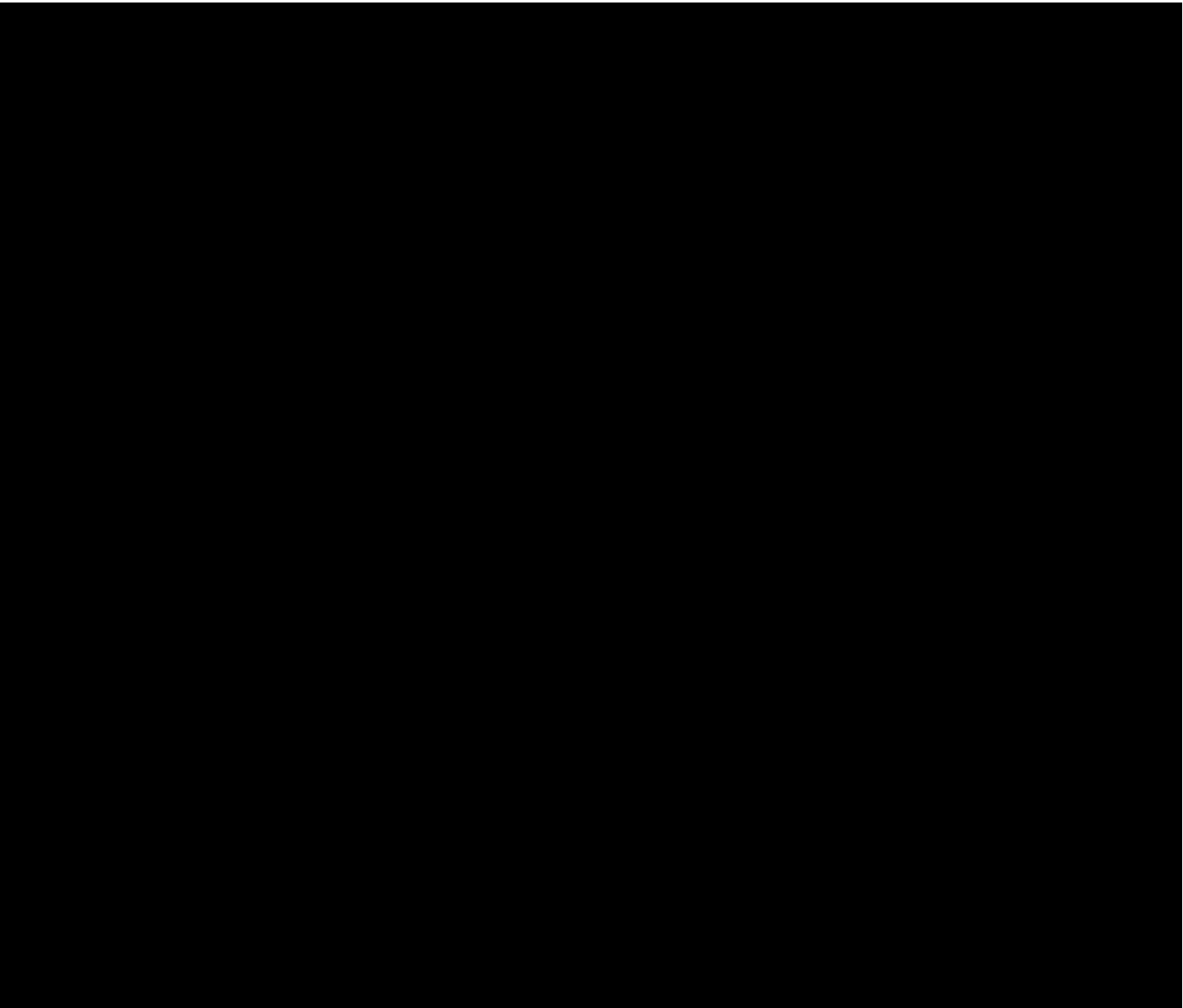
IV. CONSTRUCT ANALYSIS

A. Construction of the Submission Microorganism

[REDACTED]

[REDACTED]

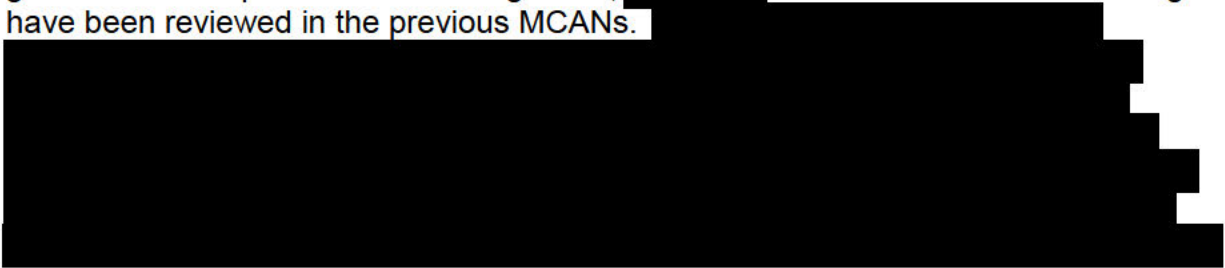
[REDACTED]





B. Potential Hazards of the Genetic Modifications

There are low hazards associated with the introduced xylose and arabinose utilization gene in the final production microorganism, [REDACTED] Potential hazards of these genes have been reviewed in the previous MCANs. [REDACTED]



these same genes does not pose concerns. [REDACTED]

The potential for horizontal gene transfer is low because all modifications were integrated directly into chromosomal DNA. The introduced genetic material is apparently stably inserted as no losses of any inserted genes have been seen in subsequent daughter generations.

V. HUMAN HEALTH HAZARDS

The concern for human health effects associated with the recipient microorganisms is low. [REDACTED] is a microorganism with an extensive history of safe use in baking, wine-making, and biotechnology. [REDACTED] is not a primary fungal pathogen causing disease in immunocompetent hosts.

The concern for pathogenicity/toxicity arising from the introduced [REDACTED] is low. There is also low concern for the introduced [REDACTED]. There is also low concern for [REDACTED]. These introduced genes would not contribute to the pathogenicity, toxicity, or allergenicity of the recipient organisms (McClung, 2016).

There is no concern for the use of antibiotic resistance genes since the four antibiotic selection markers used during construction of the submission microorganism were removed from the final constructs.

VI. ECOLOGICAL HAZARDS

There are low ecological hazard concerns for the recipient microorganism strains of [REDACTED]. [REDACTED] is ubiquitous in the environment with no known adverse effects to animals or plants or the environment. The genetic modifications done on the recipient microorganisms to arrive at the production strains do not pose ecological concerns. [REDACTED]

[REDACTED] The other intergeneric genes enabling [REDACTED] do not pose ecological concerns.

The production strain may be expected to survive in the environment if inadvertently released from [REDACTED], however, their potential survival does not pose concerns. Also, releases of the viable microorganisms from closed system manufacture and use in [REDACTED]

VIII. INTEGRATED RISK ASSESSMENT

There is low risk to human health and the environment associated with the use of the [REDACTED]

[REDACTED] These genetic modifications done to enhance the strain's ability to produce ethanol through utilization of the pentose sugars in [REDACTED]

REFERENCES

[REDACTED]

McClung, G. 2016. Construct Hazard Analysis for J16-03. Office of Pollution Prevention and Toxics. U.S. Environmental Protection Agency, Washington, DC.

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Peñalva-Arana, C. 2016. Genetic Construction Report for J16-03. Office of Pollution Prevention and Toxics. U.S. Environmental Protection Agency, Washington, DC.

Segal, M. 2016. Microbial Identification of J16-03. Office of Pollution Prevention and Toxics. U.S. Environmental Protection Agency, Washington, DC.